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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,147	10/05/2000	Tomoki Todo	066683/0188B	7711

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EXAMINER
WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
1632	18

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/679,147	TODO ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *16 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7-9,12-16,19-30,32,33,35-37,48,49 and 52-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7-9,12-16,19-30,32,33,35-37,48,49 and 52-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/16/03 has been entered. As requested, applicant's preliminary amendment received on 6/16/03 has also been entered. Applicant's preliminary amendment canceled claims 3-6, 10-11, 17-18, 31, 34, 38-47, and 50-51, and added new claim 57. Claims 1-2, 7-9, 12-16, 19-30, 32-33, 35-37, 48-49, and 52-57 are currently pending and under examination. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in previous office actions.

Claim Rejections - 35 USC § 112

Original, amended, or new claims 1-2, 7-9, 12-16, 19-30, 32-33, 35-37, 48-49, 52-54, and 57 stand rejected under 35 U.S.C. 112, first paragraph, for scope of enablement. Applicant's

amendments and arguments have been fully considered but have not been found persuasive in overcoming the instant rejection for reasons of record as discussed in detail below.

The applicant argues that the amendments to the claims renders the instant grounds of rejection moot. The office disagrees. The attachment to the advisory action stated that the applicant's claims amendments and arguments presented in the amendment after-final received on 11/18/02 have not overcome the following issues for reasons of record: 1) lack of enablement for making and using soluble co-stimulatory molecules other than B7-1-Ig or B7-2-Ig; 2) lack of enablement for the use of vectors other than HSV vectors; and 3) lack of enablement for vectors capable of "targeting" particular types of cells. Regarding issue 1), the applicant has amended claims 55-56 to recite wherein the soluble costimulatory molecule is B7-1-Ig and therefore these claims have been withdrawn from the instant rejection of record. However, claims 1-2, 7-9, 12-16, 19-30, 32-33, 35-37, 48-49, 52-54, and 57 have not been so amended and continue to read broadly on any soluble costimulatory molecule in the B7 family or any soluble B7-1 molecule. The previous office action stated that the evidence of record, i.e. the specification and publications by Kato et al., Kanner et al., Noelle et al., and Hurtado et al., while demonstrating that it was within the skill of the artisan to make a soluble co-stimulatory molecule comprising the extracellular domain of a co-stimulatory molecule and IgG, does not provide enablement for making soluble co-stimulatory molecules that do not contain IgG. The applicant's has not provided any arguments regarding this issue. Therefore, the rejection of record regarding this issue is maintained over claims 1-2, 7-9, 12-16, 19-30, 32-33, 35-37, 48-49, 52-54, and 57 .

Regarding issue 2), the applicant's amendments have overcome this grounds of rejection for claims 2, 23, 32-33, 35-37, 48-49, 54, and 57 by amending the claims to recite an HSV vector encoding the soluble B7 costimulatory factor. However, claims 2, 7-9, 12-16, 19-22, 24-30, and 52-53 have not been so limited. Claim 1, from which claims 7-9, 12-16, 19-22, and 52 depend recites a composition comprising an expressible nucleotide sequence for a soluble B7 costimulatory sequence and a herpes simplex virus vector. As such, the soluble B7 may be contained in any type of expression construct not limited a herpes simplex virus vector. Claim 24, from which claims 25-30, and 53 depend, continues to recite that the composition comprises an expressible nucleotide sequence for a soluble B7 costimulatory factor. These claims do not contain any recitation of a herpes simplex virus vector. Again, in these claims, the soluble B7 may be contained in any type of expression construct. The previous office actions have addressed in detail the unpredictability of using any and all vectors in applicant's instant invention, and the fact that the specification also does not provide an enabling disclosure for using any vector/promoter combination to express therapeutic amounts of B7-1-Ig *in vivo*, citing Verma et al., Marshall et al., Orkin et al, and Fry et al. and Roth et al. The applicant has not provided any arguments addressing this issue. Therefore, the rejection of record regarding this issue is maintained over claims 2, 7-9, 12-16, 19-22, 24-30, and 52-53.

Regarding issue 3), which concerns the targeting of the vector to tumor cells, the applicant has amended the claims to delete language regarding targeting the vector to tumor. However, the applicant has also amended the claims to delete the limitation that the composition would be

administered by localized delivery. With the exception of claims 7-9, and 25, which recite that the nucleotide sequence or composition is administered directly to the tumor, the method claims, claims 1-2, 12-16, 19-22, 24, 26-30, 52-53, and 57, read on the use of any route of administration such that the factor is expressed by tumor cells or cells in the immediate area of the tumor. The previous office actions provided substantial evidence regarding the lack of predictability in targeting vector delivery and gene expression to particular cell types *in vivo*, citing Deonarian and Miller. The applicant has not provided any arguments addressing this issue. Therefore, the rejection of record regarding this issue is maintained over claims 1-2, 12-16, 19-22, 24, 26-30, 52-53, and 57.

For the record, the following subject matter is considered to be enabled by the specification and evidence of record: 1) pharmaceutical compositions comprising a herpes simplex virus vector encoding a soluble costimulatory factor selected from the group consisting of B7-1-Ig and B7-2-Ig; and 2) methods of activating or enhancing a T-cell response in a patient with a tumor comprising administering a pharmaceutical composition comprising a herpes simplex virus vector encoding a soluble costimulatory factor selected from the group consisting of B7-1-Ig and B7-2-Ig directly into said tumor or a local area of said tumor, such that said factor is expressed by tumor cells or cells in the immediate area of the tumor, and said T-cell response thereby is activated or enhanced against said tumor.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

New claim 57 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 57 depends on claim 24. There is no antecedent basis in claim 24 for "said herpes simplex vector" as recited in claim 57.

Duplicate Claims

Applicant is advised that should claims 23 and 55 be found allowable, claims 32 and 56 respectively will be objected to under 37 CFR 1.75 as being a substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The rejection of claims 23 and 32 under 35 U.S.C. 102(a) as being anticipated by Sturmhoefel et al. is withdrawn in view of applicant's amendment to the claims which recites that the vector is a herpes simplex virus vector.

The claims as written appear to be free of the prior art of record, as the prior art of record does not appear to teach or suggest herpes simplex vectors encoding soluble B7 or B7-Ig, or methods of enhancing T cell responses in patients with tumors by administering an HSV vector encoding soluble B7.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Fri from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 872-9306. Please be advised that official faxes may no longer be received by the examiner's Rightfax number.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER